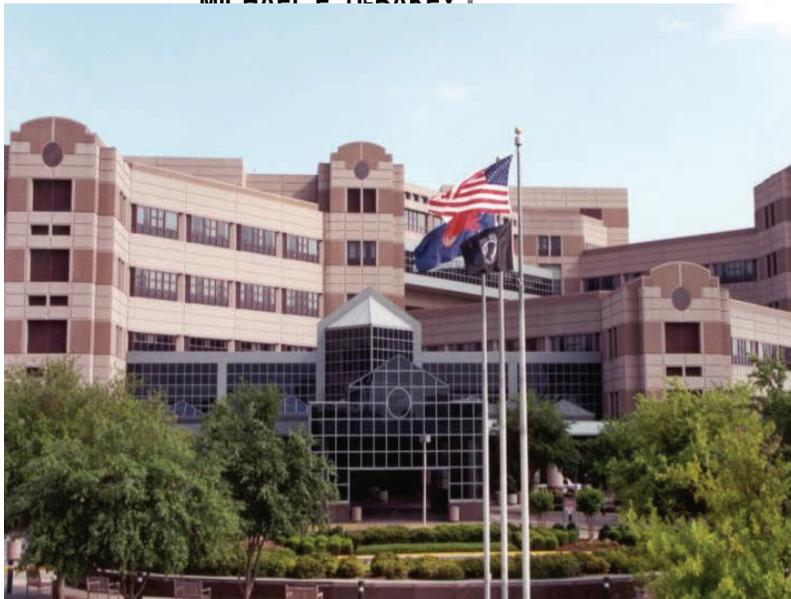




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# RESEARCH &

June 2007



**A guide to help you begin a successful research program**

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# *Getting started*

## **Will you be working in building 109 or 110?**

- ✓ These buildings have keycard access only 24/7.
- ✓ Key cards can be obtained from Marcie Jager in MEDVAMC R&D office (Ext. 7565, Bldg. 110, room 318)
- ✓ Key cards are also needed to access the vivarium. To access the vivarium, you should be listed on an animal protocol.
- ✓ You must complete Animal Subject Training before receiving access to the vivarium (contact Pam Maseda about your training X7567.)

## **Need keys for your lab?**

- ✓ Contact Mary Abbott in MEDVAMC R&D office (Ext. 7566) and give her the room # and the lock #. She will order the keys. You must pick them up in the main building, 4th floor in Facilities, 4A-368.
- ✓ If you are WOC, a VA-paid person will have to sign the keys out on your behalf.

## **Registering new personnel**

- ✓ If you are WOC (Without Compensation, i.e. paid by BCM), you will need to fill out paperwork with Marcie Jager in the MEDVAMC R&D office (Bldg. 110, room 318). She will help you get badges, keycards, etc.

## **To place a Work Order**

- ✓ Contact Mary Abbott (Ext. 7566) for work orders regarding plumbing, electrical problems, etc. If she is not available, call Marcie Jager (Ext. 7565) or Debra Huff (Ext. 7606.)
- ✓ If there is an emergency, you can call Engineering directly at their hotline Ext. 5884. However, follow up by calling someone in the Research Office so we can fill out the work order and help you keep track of its status.

## Computer access

- ✓ Nestor Ramirez (Ext. 7359) can help you set up access to the VA Intranet and the Internet, or to the Gigaman .

The **Gigaman connection** allows us to connect directly to BCM's Intranet, and through them to the Internet.

Accessing the Internet through the Gigaman connection gives you more flexibility.

- ✓ You have more choices of which operating system to use.
- ✓ You will have administrator privileges on your own computer and can add any properly licensed software that you need.
- ✓ You can set up workgroups within your research team to share files.
- ✓ You can network to your printer.
- ✓ You have broader access to e-journals at the library without using the BCM proxy.

**Remember that computers on the Gigaman are bound by Baylor's Internet use policies.**

- ✓ BCM web page lists their policies for the types of sites visited, nature of emails sent, commercial use, etc.
- ✓ You must keep up-to-date versions of an antiviral program on your computer at all times. You can download these for free from BCM.

**Your responsibilities on the Gigaman include:**

- ✓ You must update your viral definitions regularly. See instructions for setting computer to do this automatically. It is all free.
- ✓ You must update your security patches. Notices of new patches are usually posted on the BCM announcements page.
- ✓ You will not be able to backup files on the VA's computer and will need to arrange your own backup system

**If you want to access CPRS or VISTA, you will need to do this from a VA computer, connected to the VA network, and configured/maintained by MEDVAMC IMS.**

# Getting Approval to do Research at the

**Our web page can be accessed via both the BCM and the VA intranet.**

**If you access via the BCM intranet you need a BCM email account and password to access it.**

- ✓ Select "Research" from the BCM Intranet.
- ✓ Select "Research Centers" under the General Resources title.
- ✓ Scroll down to Michael E. DeBakey VA Medical Center Research & Development.
- ✓ Select and bookmark it for faster access in the future.

**To access our web page via the VA intranet:**

- ✓ From the VA homepage: <http://vawww.houston.med.va.gov>
- ✓ Select "Hospital Service Lines".
- ✓ Scroll down to Research Service Line.
- ✓ Select "VA Research and Development" and bookmark it for faster access in the future.

**If research involves the VA, it must be approved by the Research and Development (R&D) Committee before it starts.**

- ✓ Protocols need approval from the R&D Committee if they:
  - Will recruit veterans as subjects.
  - Take place in facilities located at the VA or in approved off-site locations , or
  - Are conducted by VA and non-VA Investigators while on duty at VA facilities or approved off-site locations.

**Research & Development**

To expedite the process, submit your protocol to the VA R&D at the same time as it is submitted to the IRB or IACUC and other safety



**Research & Development**

**Once your protocol is approved, it will be assigned a number. You will be contacted annually to determine whether the project should remain active.**

**Research supported by the VA, whether directly by grant funds, or indirectly through the use of VA patients and/or VA facilities, should be acknowledged in all publications.**

- ✓ If you are a VA employee, note this in your publications, interviews, and presentations.
- ✓ If you used facilities at the VA, or you used veterans in your research, acknowledge the VA. It helps everyone in the long run.
- ✓ Investigators in Health Services Research should refer to the policies on the HSR&D Center of Excellence intranet web site (ePRIDE.)

**The VA requires annual training in a variety of topics including safety issues, privacy, ethics, etc.**

- ✓ Links for most of these training programs are located on the MEDVAMC R&D web page.

**When veterans are enrolled in a research project, this should be noted in their electronic medical record.**

- ✓ If the study involved an intervention such as a study drug, the record in CPRS should have a flag to alert other clinicians that may provide care for this same veteran. See the instruction on the MEDVAMC R&D web page.

**Investigators with questions about biosafety, radiation, hazardous agents, and general preparation of protocols for R&D may contact Pam Maseda, Staff Assistant.**

- ✓ Pam can be reached at Ext. 7567 or email: [pmaseda@bcm.edu](mailto:pmaseda@bcm.edu) or at her Outlook email address: [Pamela.maseda@va.gov](mailto:Pamela.maseda@va.gov)

**Fannie Jackson, Science Information Officer, is a good resource for investigators who have general questions about protocol preparation.**

- ✓ Fannie can be reached at Ext. 7918 or email: [fanniej@bcm.edu](mailto:fanniej@bcm.edu) or [jackson.fanniem@va.gov](mailto:jackson.fanniem@va.gov)

**Marilyn Crosby, RN, Research Compliance Nurse, is a good resource for investigators who have questions about clinical research, coordinators, etc. as they prepare their protocol.**

- ✓ Marilyn can be reached at Ext. 8096 or email: [marilyn.crosby@va.gov](mailto:marilyn.crosby@va.gov)

**Unique & specific steps for submitting a grant proposal at the HSR&D Center of Excellence (Houston Center Quality of Care and Utilization Studies):**

- ✓ Contact the Grants Management and Compliance Pre Award Grant Manager (Rhonda O'Donovan) at 713-794-8601 and she will give the investigator a timeline that will include the following milestones:
  - **Three and a half months** before the grant due date submit a VACS form electronically to Pamela Maseda at [pmaseda@bcm.tmc.edu](mailto:pmaseda@bcm.tmc.edu).
  - **Three months** before the grant due date the investigator must meet with Grants Management and Compliance Pre Award Grant Manager (Budget and IRB issues), Chief of Design and Analysis (Programming and Statistical Support), Chief of Information Technology (Computing Costs and Equipment) and Chief of Project Staff (Research Assistant Support) to prepare a grant budget.

## Unique & specific steps for submitting a grant proposal at the HSR&D Center of Excellence (continued from p 7)

- **Two months** before the grant due date the investigator must submit the science, budget and budget justification portions of the grant application to the HSR R&D Sub-Committee for external review.
- The HSR Subcommittee meets on the third Thursday of the month. Protocols are due on the 1<sup>st</sup> of the month.
- **One month before the grant due date the investigator must have their budget approved by the Budget Committee.**
- **Ten business days** before the grant due date the investigator must submit the final copy of the grant application to the Grants Management and Compliance Pre Award Grant Manager. The Pre Award Grant Manager will get final approvals and institutional signatures.

For all non-VA grants, the grant application is routed through the Department of Medicine and the Office of Research at Baylor College of Medicine. For all VA grants, the grant application is routed through the ACOS of Research and Development for the Houston VA Medical Center.

- **Five business days** before the grant due date the Pre Award Grant Manager will create the final copy of the grant and send the original and the appropriate amount of copies to the funding agency by 12:00 p.m. via Federal Express.

Research Service Line (151)  
2002 Holcombe Blvd.  
Houston, TX 77030  
Phone: 713-794-7566  
Fax: 713-794-7938

## Additional Subcommittees that might need to review your research

### Will the protocol involve human subjects?

- ✓ See submitting a protocol to BCM IRB.

### Will the protocol involve animal subjects?

- ✓ See submitting a protocol to BCM IACUC.

### Will you use biohazardous agents, hazardous chemicals, or radioisotopes in your laboratory?

- ✓ Complete the relevant form (see MEDVAMC R&D web page) and submit to the VA Subcommittee on Research Safety.
- ✓ The R&D committee will not finalize your approval until the Subcommittee on Research Safety has approved the project.

### Will your research involve use of radiation and/or radiographic exams?

- ✓ Complete the VARADPC form (clinical studies) or the VARADNC form (non-clinical studies) (see MEDVAMC R&D web page).
- ✓ The critical issue is whether the test is a necessary part of the research protocol. For example, if a CXR is a required screening test and you will order a CXR on any patient who does not already have one, then the CXR becomes part of the research..
- ✓ Be sure the radiation risks associated with X-ray exams are listed in the IRB consent form.

### Will your protocol involve use of biohazardous agents in animals?

- ✓ Complete the IACUC protocol in BRAIN and submit the required paperwork to Baylor's Institutional Biosafety Committee.
- ✓ If you are using radioactive agents in animals, you will need approval from the VA's Radiation Safety Committee as the MEDVAMC is not covered by Baylor's radiation license but reports directly to the NRC.

**Will your protocol involve the use of recombinant DNA/gene therapy in humans?**

- ✓ Use of recombinant DNA in human subjects requires a specialized level of review. In this case, the VA's Subcommittee on Research Safety collaborates with Baylor's Institutional Biosafety Committee and you will need to fill out paperwork for Baylor's review.

## Institutional Review Board (IRB)

**MEDVAMC uses Baylor College of Medicine's IRB as our IRB. Approval must be obtained from BCM IRB before research can start.**

**Be sure and list the VA as one of the performance sites if you plan to recruit veterans, if the study takes place in facilities located at the VA or approved off-site locations, or if you, as a VA employee (VA paid or WOC), will be doing the research.**

**BCM has six IRBs that meet throughout the month.**

- ✓ Your protocol will be assigned to the earliest possible meeting.
- ✓ Baylor's goal is to return comments within two weeks of submission.
- ✓ In practice, anticipate that approval will take a minimum of six weeks.

## Submitting protocols to BCM IRB

**The VA has a special consent form (10-1086).**

- ✓ BRAIN will generate this automatically when you list the VA as a performance site.

**Be sure that the VA consent form lists a VA physician for patients to contact in case of emergencies.**

**Nestor Ramirez will assist you if you experience problems with viewing or printing consent forms.**

- ✓ Nestor can be reached at Ext. 7359 or email: nestor.ramirez@va.gov or nestorr@bcm.edu

**To submit a human studies protocol in BRAIN, you will need to complete a web-based tutorial in human subject protection.**

- ✓ This is also available in BRAIN under "e-CAT".
- ✓ There are multiple modules.
- ✓ Once all modules have been completed, your certification is valid for three years.

**Baylor's human subject protection training can substitute for the VA's required Human Subject Protection and Good Clinical Practices Training.**

- ✓ However, the VA requires annual updates, so in years 2 and 3 you will need to complete the VA's Human Subject Protection and Good Clinical Practices training (see MEDVAMC R&D web page).

**Any Serious Adverse Event (SAE) must be reported to the VA via email to this address: vaae@bcm.edu in addition to the BCM IRB.**

## **Submitting protocols to BCM IACUC**

**MEDVAMC uses Baylor College of Medicine's IACUC as our IACUC.**

- ✓ Research cannot start until the BCM IACUC approves the project.

**BCM has one IACUC that meets monthly.**

- ✓ See BCM Research web page for the submission deadlines (generally the 1st of the month.)
- ✓ In practice, anticipate that approval will take a minimum of 6-8 weeks.
- ✓ Discussing your project ahead of time with one of the Baylor's Center for Comparative Medicine (CCM) veterinarians is a good strategy to identify and solve potential areas of controversy in the review of your protocol.
- ✓ See CCM web page under BCM's Office of Research web page on the BCM Intranet for additional information and copies of CCM's policies.

**There is mandatory web-based training in animal research for all individuals working on the protocol that must be completed before the project is approved.**

- ✓ See e-CAT under BRAIN.

**If you are housing animals at the VA, be sure and list the VA as one of the performance sites.**

- ✓ Don't just list VA under the "housing", list as performance site also.
- ✓ If you are a VA investigator housing animals elsewhere, it is important that you still select VA as one of the performance sites.

**If you are submitting a grant for funding to VA Central Office, you will need to fill out a VA-specific animal form called ACORP in addition to your protocol in BRAIN.**

- ✓ The BRAIN protocol and ACORP form should contain identical information.
- ✓ Attach the ACORP form electronically to the BRAIN protocol and submit the two together.

## General comments about BRAIN

<https://brain.bcm.edu/brainlogin.asp>

**BRAIN (Biomedical Research Assurance and Information Network) is a web-based system for:**

- ✓ Submission of protocols to IRB
- ✓ Submission of protocols to the IACUC
- ✓ Training in human subject protection and animal handling
- ✓ Submission of conflict-of-interest statements regarding your research
- ✓ Submission of grant proposals for routing through your department and through the Office of Research for signatures and budget review

**You will need a BCM email account/password to access the BRAIN.**

- ✓ Your departmental administrator at BCM should be able to help you with this.

### To log in to BRAIN

- ✓ Select "Research" from BCM Intranet (amongst headings in banner mid-way across the page)
- ✓ Select "BRAIN" from left-hand column of entries
- ✓ Log in using your BCM email account log-in and email password.
- ✓ Be sure your computer is configured for "HTTP 1.1 through proxy" as per instructions mid-way down page
- ✓ Select ESP-1 for animal and human research protocols.
- ✓ Select ESP-2 for submission of grant proposal routing sheets
- ✓ Select e-CAT for on-line training
- ✓ Select e-COI for conflict of interest.

**If you want to start a protocol before you arrive in Houston:**

- ✓ Ask your department for a BCM email account.
- ✓ Submit your protocol under a colleague's name (such as your chairman's). Notify IRB or IACUC by email of your plan.
- ✓ Once you get your BCM faculty appointment, you can transfer the protocol from your chairman's name to yours using the amendment function in BRAIN. Again, notify the IRB or IACUC staff so they can facilitate the process.

**BCM has classes on the use of BRAIN; the training icon is the first item under the heading "General Notices." Click on the words BRAIN training to view the training modules available.**

**Any BCM faculty or staff can log in to BRAIN and prepare a draft of your protocol. However, only the PI can submit it. This submission is done electronically and serves as your "signature".**

**Once the protocol is in draft form, select "Privileges" to add the names of other individuals who should have read or read/write privileges on your protocol.**

- ✓ You can also indicate the names of persons, such as admin support, who should receive email notification about changes in the status of the protocol (e.g., need for revision or renewal).

**After you submit the protocol, the IRB or IACUC will often ask for revisions or clarifications.**

- ✓ You will be notified by email that action on your protocol is needed.
- ✓ Be on the lookout for these emails. They come from “brainmail” and the subject starts with “ESP-1”.
- ✓ Log into BRAIN and click on your protocol to find the memo listing the needed modifications.
- ✓ Your prompt reply is critical to getting your protocol processed quickly.
- ✓ You can log in at any time and check the status of your protocol under BRAIN.

**BRAIN can generate reports that identify which of your protocols are nearing renewal deadlines. See “Reports” section.**

**When your protocol is nearing expiration, you will receive email reminders to renew it.**

- ✓ Renew promptly.
- ✓ If your protocol expires, your research must stop and you will have to initiate a new protocol and start the approval process de novo.
- ✓ You can make changes at time of renewal. However, filing an amendment will **NOT** renew the protocol.

**Contact the IRB and IACUC staff by email if you have unusual problems. They are there to help.**

## MEDVAMC RESEARCH COMMONS

The Research Commons is a resource available to all researchers, located on 5D of the main hospital.

### Exam and Meeting rooms.

- ✓ Waiting room.
- ✓ Four double patient rooms.
- ✓ One single exam room with reverse isolation.
- ✓ Patient interview/Monitor audit room.
- ✓ Meeting room.
- ✓ Kitchenette

### Administrative Support

- ✓ Security record storage for those without VA space.
- ✓ Four VA workstations connected to VA intranet and internet.
- ✓ Clerical support for scheduling VA tests, scanning consents into CPRS
- ✓ Patient receptionist between 8:30 AM and 1:00 PM.

### Specimen Collection & Processing.

- ✓ Blood draw room.
- ✓ Specimen Processing Lab
- ✓ -70°C freezer (short term storage)
- ✓ -20°C freezer (short term storage)
- ✓ Refrigerator
- ✓ Ice Machine
- ✓ Dry Ice
- ✓ Refrigerated swinging bucket centrifuge
- ✓ Fixed angle non-refrigerated centrifuge

**Pat Cloud is the Commons Manager. Please contact Pat to schedule and use any of the resources in the Research Commons. Pat can be reached at Ext. 7001 or via email at [pcloud@bcm.edu](mailto:pcloud@bcm.edu) or [Patricia.cloud@va.gov](mailto:Patricia.cloud@va.gov). Pager # 713-794-7134 ext. 1431.**

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**Research & Development**

## NOTES

## NOTES

